Kansas Medical Assistance

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

September 09, 2004

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita Room Topeka, Kansas September 09, 2004	**Members Present By Phone:** Michael Burke, M.D., Ph.D., Chair; R. Kevin Bryant, M.D., CMD; Dennis Grauer, Ph.D.; Linda Kroeger, ARNP; John Lowdermilk, R.Ph.; Barry Sarvis, R.Ph. Brenda Schewe, M.D.; Roger Unruh, D.O.; Kevin Waite, PharmD **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A.; Mary Obley, R.Ph.; Vicki Schmidt, R.Ph., DUR Program Director; Erica Miller **EDS Staff Present:** Nicole Garcia, R.N.; Chalen Reed, R.Ph.; Debra Quintanilla, R.N.	**Representatives:** Randy Blackwell (Biovail Pharmaceuticals), Kate Kulesher (Wyeth), Hoa Pham (Amgen), Mike Hutfles (Kansas Government Consulting), Bruce Steinberg (Sanofi-Aventis Pharmaceuticals), Diana Morasch (AstraZeneca), Danny Ottosen (Bertek), Jason Neef (Sepracor), Mike Moratz (Merck), James Lieurance (Takeda), Tom Rickman (Aventis), Rhonda Clark (Purdue), Lynn Nagorski (Purdue), Jim Baumann (Pfizer)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:35a.m via phone conference.	
II. Review and Approval of July 14, 2004, Meeting Minutes	• Vicki reviewed the suggestions that were made by the DUR Board members. Under Discussion: Page 4, 3rd bullet, change 3rd sentence to "Suggestions include listing patients that are less than 65 with a need for anti-inflammatory analgesia and list GI diagnosis." Page 5, 1st bullet, 1st sentence change cost to incidence. Page 5, 2nd bullet, change to "Dr. Burke	• A motion to approve the minutes with the corrections was made by Dr. Schewe and seconded by Dr. Unruh. The motion carried unanimously by roll call.

	suggested trying to get clinical data regarding the incidence of GI bleeds." Page 5, 5th bullet, 1st	

TOPIC	DISCUSSION	DECISION/ACTION
Review and Approval of July 14, 2004, Meeting Minute – Con't	sentence change "have a GI problem" to "meet PA criteria" and delete everything after "The DUR Board agreed." Page 6, 2nd bullet, change 3rd sentence to "Dr. Burke stated that was correct, it has been changed to patients needing anti-inflammatory analgesia." Under Decision/action: Page 6, 1st bullet, change 5th sentence to "PA requests for consumers taking inhaled corticosteroid therapy (i.e. Advair® or similar inhalers) does not meet the current criteria which is specific for concomitant oral corticosteroid therapy."	
III. New Business **A. Etanercept (Enbrel®)** **1. Discussion of Prior Authorization**	• Dr. Burke pointed out that there is a new indication for Enbrel. • Mary and Vicki reviewed the changes that were made to the Prior Authorization (PA) criteria. • Dr. Schewe asked if there is a different form for renewals. Mary stated that the forms are the same. Deb stated that the physician needs to write renewal on the renewal form. • Vicki stated that most Rheumatologist and Dermatologist are used to the PA for Enbrel®.	
2. Public Comment	• No public comment.	
3. DUR Board Recommendations	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Waite and seconded by Dr. Bryant to accept the SRS recommended Etanercept (Enbrel®) criteria: Must meet all of the following: 1) One of the following diagnosis: A) Moderate to severe, active rheumatoid arthritis B) Active Polyarticular juvenile rheumatoid

TOPIC	DISCUSSION	DECISION/ACTION
Etanercept (Enbrel®) – Con't		arthritis C) Active psoratic arthritis D) Active Ankylosing Spondylitis E) Chronic moderate to severe plaque psoriasis (18 years or older) **AND** 2) Documentation of inadequate response to one or more conventional DMARDs (Disease modifying antirheumatic drugs) – with exception of either active Ankylosing Spondylitis (which requires two or more NSAIDs previously) OR Psoriasis (which requires patients to be candidates for systemic therapy or phototherapy). **AND** 3) Be prescribed by a Rheumatologist or Dermatologist **AND** 4) Evaluation for latent tuberculosis infection with TB skin test **Warning:** Increased risk of serious infections and lymphomas Prior Authorization will be approved for six (6) months. The motion carried unanimously by roll call.
B. Discussion/Approval of PDL and Resulting PA Criteria for Non-preferred Drugs **1. Triptans** **a. PDL Advisory Committee Recommendations**	• Dr. Burke stated that the PDL Committee found all Triptans to be clinically equivalent.	

TOPIC	DISCUSSION	DECISION/ACTION
Triptans – Con't		
b. SRS Proposal for Preferred Drug and PA Criteria	• Mary stated that the only change made to the Triptans class is Almotriptan Malate (Axert®) was moved from the Non-Preferred Drugs that do require PA to Preferred Drugs that do not require PA. This change will be effective at the end of October or the beginning of November. The recommendation from SRS is for Almotriptan Malate (Axert®), Rizatriptan Benzoate (Maxalt®, Maxalt-MLT®), and Sumatriptan (Imitrex®) to be the preferred Triptans, and PA required for Frozatriptan Succinate (Frova®), Naratriptan HCL (Amerge®), Zolmitriptan (Zomig®, Zomig ZMT®, Nasal Spray) and Eletriptan-HBr (Relpax®). • Dr. Burke pointed out that Sumatriptan was left as a preferred drug at the request of the PDL committee. • Mary reviewed the changes that were made to the PA forms. The three boxes at the bottom have changed slightly. The first box now states to provide clinical symptoms instead of please specify and the please specify line has been removed from the second box.	
c. Public Comment	• No public comment.	
d. Discussion	• No Board discussion.	
e. DUR Board Recommendations	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Unruh and seconded by Dr. Grauer to accept the SRS recommendation for Almotriptan Malate (Axert®), Rizatriptan Benzoate (Maxalt®, Maxalt-MLT®), and Sumatriptan Succinate (Imitrex®) to be the Preferred Triptans, and PA required for Frozatriptan Succinate

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Triptans – Con't		(Frova®), Naratriptan HCL (Amerge®), Zolmitriptan (Zomig®, Zomig ZMT®, Nasal Spray), and Eletriptan-HBr (Relpax®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
2. Calcium Channel Blocker (Dihydropyridines)		
a. PDL Advisory Committee Recommendations	• Dr. Burke stated that the PDL Committee found clinical equivalence in all Dihydropyridines Calcium Channel Blockers.	
b. SRS Proposal for Preferred Drug and PA Criteria	• Mary stated that the recommendation from SRS is for Amlodipine (Norvasc®), Isradipine CR (Dynacirc CR®), Nifedipine CC (Adalat CC® & generic equivalents), Nicardipine (Cardene®) to be the Preferred Dihydropyridines Calcium Channel Blockers, and PA required for Nifedipine(Adalat®, Procardia®, & generic equivalents), Nifedipine XL (Nifedical XL®), Procardia XL (Nifedipine SR OSM® & generic equivalents), Nimodipine (Nimotop®), Nisoldipine (Sular®), Felodipine (Plendil®), Isradipine (Dynacirc®), and Nicardipine.	
c. Public Comment	• No public comment.	
d. Discussion	• Dr. Burke pointed out that Nifedipine was moved to non-preferred status at the request of the PDL Committee due to safety issues. Mary stated that many patients are on Amlodipine, so this change will not affect many people. • Mr. Sarvis asked what the effective date for these	

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CCB (Dihydropyridines) - Con't	changes is. Mary stated that the changes will be effective on November 1, 2004, pending the rules and regulations process. • Dr. Waite pointed out that it is confusing to have one product of Dynacirc® on the PDL and the other product on the non-PDL. He suggested sending out a newsletter pointing out the changes. Dr. Burke also suggested placing the changes on the first page of the DUR newsletter. Mary stated that this could be included in the bulletins that all providers receive the DUR bulletin, and that she could list the changes on the website as well.	
e. DUR Board Recommendations	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Mrs. Kroeger and seconded by Dr. Schewe to accept the SRS recommendation for Amlodipine (Norvasc®), Isradipine CR (Dynacirc CR®), Nifedipine CC (Adalat CC® & generic equivalents), and Nicardipine (Cardene®) to be the Preferred Dihydropyridines Calcium Channel Blockers, and PA required for Nifedipine (Adalat®, Procardia®, and generic equivalents), Nifedipine XL (Nifedical XL®), Procardia XL (Nifedipine SR OSM® & generic equivalents), Nimodipine (Nimotop®), Nisoldipine (Sular®), Felodipine (Plendil®), Isradipine (Dynacirc®), and Nicardipine SR (Cardene SR®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.

TOPIC	DISCUSSION	DECISION/ACTION
3. Calcium Channel Blockers (Non-Dihydropyridines)		
a. PDL Advisory Committee Recommendations	• Dr. Burke stated that the PDL Committee found clinical equivalence in all Non-Dihydropyridines Calcium Channel Blockers.	
b. SRS Proposal for Preferred Drug and PA Criteria	• Mary stated that the recommendation from SRS is for Diltiazem (Cardizem®, generic equivalents, Tiazac®, Diltia XT®), Verapamil (Isoptin®, Isoptin SR® & generic equivalents, Calan®, Calan SR®, generic equivalents, and Verelan®) to be preferred Non-Dihydropyridines Calcium Channel Blockers, and PA required for Diltiazem XR (Cardizem SR®, Cardizem CD®, Cardizem LA®, Cartia XT®, Dilacor XR®, & Taztia XT®), Covera-HS®, Verelan PM®. Mary pointed out that the only change is Taztia XT® was added to Non-preferred.	
c. Public Comment	• No public comment.	
d. Discussion	• No Board discussion.	
e. DUR Board Recommendations	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Dr. Waite to accept the SRS recommendation for Diltiazem (Cardizem®, generic equivalents, Tiazac®, Diltia XT®) and Verapamil (Isoptin®, Isoptin SR® & generic equivalents, Calan®, Calan SR®, generic equivalents, & Verelan®) to be the Preferred Non-Dihydropyridines Calcium Channel Blockers, and PA required for Diltiazem XR (Cardizem SR®, Cardizem CD®, Cardizem LA®, Cartia XT®, Dilacor XR®, & Taztia XT®), Covera-HS®, and Verelan PM® with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred

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CCB (Non -Dihydropyridines) - Con't		Drug, or absence of appropriate formulation or indication of the drug. The motion carried unanimously by roll call.
C. Elect New DUR Board Chair	• Vicki stated that the reason we are electing a new chair now is we are trying to line up the new Board Chair with the Federal Fiscal Year. Everyone has appreciated the work that Dr. Burke has put forth the past year. • Dr. Burke stated that the Board is open for nominations.	• Mr. Lowdermilk nominated Dr. Burke and Dr. Schewe seconded the nomination. The nomination carried unanimously by roll call.
D. Additional Announcements	• Dr. Burke announced that the next DUR meeting will be November 10, 2004 and the next PDL meeting will be October 7, 2004. • Vicki announced that there has been some concern from the pharmaceutical representatives regarding receiving information about pricing, coverage, and additional information. EDS has set up an e-mail address: pharmaceutical.drug.reps@ksxix.hcg.eds.com and phone numbers: 785-274-5940, 785-274-5969, and 785-274-5404 to answer pharmaceutical representatives questions. The e-mail address and phone numbers are for pharmaceutical representatives only. Vicki also pointed out that the November meeting will be busy due to the annual assessment from Heritage and that she appreciates the DUR Board member's flexibility. • Dr. Burke questioned whether the new PA forms will have the pharmacy help desk phone number. Vicki stated that they would have the toll free pharmacy help desk phone number. • Dr. Schewe asked when the changes made in	

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Additional Announcements – Con't	• July to the PPI would go into effect. Mary answered November 1, 2004, pending the rules and regulations process. • Dr. Burke questioned whether the public thought the arrangements for this meeting was fine. Vicki stated that if the public had to present information it would not be very effective, but since the agenda was short and to the point it worked out.	
VI. Meeting Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Schewe to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 10:10 a.m.